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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,660	11/29/2001	Paul James Davis	C7535(V)	7543
201	7590	05/20/2004	EXAMINER	
UNILEVER PATENT DEPARTMENT 45 RIVER ROAD EDGEWATER, NJ 07020			RAO, MANJUNATH N	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,660

Applicant(s)

DAVIS ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-29-01</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-13-04 has been entered.

Claims 18-25 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 3-8-04 have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shoseyov et al. (US 5,719,044, 2-17-1998), Schulein et al. (WO 94/07998, 4-14-1994) and Linder et al. (PNAS, 1996, Vol. 93:12251-55) and the common knowledge in the art regarding making antibodies through camelization procedure (see Hamers et al., WO 94/25591, 11-10-94, listed in the IDS).

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This rejection is based on obviousness due to the public availability of a printed publications.

Claims 18-25 of the instant application are drawn to a detergent composition comprising a fusion protein comprising CBD and a domain having a high binding affinity for another ligand with a binding equilibrium constant of less than 10^{-4} M, and wherein the high binding affinity domain is an antibody or a fragment of an antibody which is multispecific and which binds to a benefit agent, a fabric or a specific part of a fabric or micro-particles of unknown chemical make-up loaded with benefit agent, wherein the CBD is obtained from a variety of fungi such as *T.reesei* or bacteria such as *Clostridium*, wherein the high binding domain antibody is heavy chain antibody as found in Camelidae, or obtained from V_h fragments by camelization process, wherein the high binding affinity domain (antibody) directed to a benefit agent selected from a group as recited in claim 22, wherein the CBD and the high binding domains are linked by means of a linker consisting of 2-15 amino acids and a method of delivering a benefit agent comprising the above fusion protein to a fabric.

Shoseyov et al. teach an identical fusion protein comprising a CBD obtained from *Clostridium* and a high affinity binding domain, wherein the high binding domain is an antibody of heavy chain type directed to proteins and hormones (see column 4, lines 45-58 or claims 4-5 and figure 12), and wherein the CBD and the high affinity binding domain are linked by means of (cleavage site) linker (see column 5 lines 24-33). However, the reference does not teach a fusion protein comprising the CBD from *T.reesei* or the use of such a hybrid protein for use in detergents or teach of delivering a benefit agent using such a detergent comprising such fusion protein. The reference also does not teach that chemical equilibrium constant between the high

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affinity binding domain and its ligand (basically the binding constant between the antigen and its antibody) is lower than 10^{-4} M.

Schulein et al. teach use of proteins comprising cellulose binding domain and a catalytic domain --both of which are linked through a linker amino acid sequence comprising 2-15 amino acids—in detergent compositions and method of delivering such composition to fabrics. Thus it appears that the use of fusion proteins comprising CBDs in detergent compositions was well known in the art. To that effect, those skilled in the art can find a number of publications which are directed towards the methods of making and using hybrid proteins comprising different CBDs in detergent composition for delivering a benefit agent to a fabric.

Linder et al. teach CBD of *T.reesei*. The reference teaches that the *T.reesei* CBD exhibits reversible binding to crystalline cellulose, can be eluted from cellulose by simple dilution and that the binding is temperature sensitive with an increased affinity at lower temperatures.

With the teachings of the above references in hand it would have been obvious to one of ordinary skill in the art to make a fusion protein as taught by Shoseyov et al. but comprising *T.reesei* CBD linked to an antibody raised against a benefit agent of interest. More specifically, using the teachings of Schulein et al. that fusion proteins comprising CBDs can be used in a detergent and delivered to a fabric, it would have been obvious to those skilled in the art to make a fusion protein comprising the *T.reesei* CBD taught by Linder et al., linked to an antibody raised against a micro particle loaded with a benefit agent such as a bleach generating system (a peroxidase enzyme) by the camelization process and use it in a detergent composition along with a surfactant. One of ordinary skill in the art would have been motivated to do so as there is huge

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commercial value for such selectively acting detergent compositions. One of ordinary skill in the art would have been further motivated to use the *T.reesei* CBD as the above reference further teaches that the binding is reversible and temperature sensitive which makes it easier to set the conditions for binding and elution. One of ordinary skill in the art would have a reasonable expectation of success since Schulein et al. teach the use of fusion proteins in detergent compositions, Shoseyov et al. teach a method of making fusion protein comprising a CBD and a high binding affinity domain and Linder et al. teach the CBD from *T.reesei*.

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

Applicants may argue that the above reference (specifically that of Shoseyov et al.) does not address the chemical equilibrium constant between the high affinity binding domain and its ligand to be lower than 10^{-4} M. However, such an argument would not be persuasive to overcome the rejection because as the fusion proteins are so closely related Examiner takes the position that the fusion protein in the reference inherently has all the features of the fusion protein claimed in the instant invention even though such limitations are not clearly mentioned in the reference. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

In response to the previous Office action, applicant has traversed the above rejection arguing that Shoseyov et al. teaches a fusion protein which *may* comprise a CBD and a second protein and that the reference teaches diagnostics or immunoassay methods etc. Examiner respectfully disagrees with such an argument. The reference clearly teaches and even claims a fusion protein that comprises a CBD and a fusion partner that is a protein or an antibody. Applicant continues the argument that the reference does not teach chemical equilibrium constant or the binding of the antibody fragment to a benefit agent. Examiner again respectfully disagrees with such an argument. This is because Examiner has based his rejection on inherency and argued that even though the reference does not specifically recite the equilibrium constant for the antibody and its antigen binding, such constant is inherent to any given antigen-antibody binding and therefore such binding constant is inherent to the fusion protein taught by Shoseyov et al. Applicant again argues that none of references teach or suggest an entity comprised of CBD, antibody or antibody fragment or antibody binding to benefit agent. Here again Examiner respectfully disagrees with applicant's argument. Shoseyov et al. clearly teach a fusion protein

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(an entity) comprising a CBD and an antibody. Therefore, for all the reasons above, Examiner continues to maintain the above rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 17 of U.S. Patent 6,586,384 and claims 1, 14 and 16 of US Patent 6,579,842. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 25 of the instant application and claims 1-3 and 17 (of U.S. Patent 6,586,384) and claims 1, 14 and 16 (of US Patent 6,579,842) of the reference patents are both directed to method of delivering a benefit

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agent to a fabric by treating it with a composition comprising the binding molecule wherein the binding molecule is a fusion protein comprising a domain which binds to a fabric, i.e., a cellulose binding domain and a domain having a high binding affinity to another ligand. In the method claimed in the instant application and in the reference application there are identical steps and materials (i.e., fusion protein) used. The portion of the specification that supports the recited method claimed in claims 1-3 and 17 (of U.S. Patent 6,586,384) and claims 1, 14 and 16 (of US Patent 6,579,842) of the reference patents includes embodiments that would anticipate the method claimed in the instant application. Claim 25 of the instant application listed above cannot be considered patentably distinct over claims 1-3 and 17 (of U.S. Patent 6,586,384) and claims 1, 14 and 16 (of US Patent 6,579,842) of the reference patents when there is specifically recited embodiment that would anticipate mainly claim 25 of the instant application.

Alternatively, claim 25 cannot be considered patentably distinct over claims of the reference patents when there is specifically disclosed embodiment in the reference patents that supports claims of those patents and falls within the scope of claim 25 herein because it would have been obvious to one having ordinary skill in the art to modify claims of the reference patents by making it more broader. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims of the reference patents.

Claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8-9 and 25 of U.S. Patent application No. 09/742,689 (US Pub 20010039250). An obviousness-type double patenting rejection is

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appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 25 of the instant application and claims 1-3, 8-9 and 25 of the reference application are both directed to method of delivering a benefit agent to a fabric by treating it with a composition comprising the binding molecule wherein the binding molecule is a fusion protein comprising a cellulose binding domain (the domain that binds to cellulose fibers) and a domain having a high binding affinity to another ligand. In the methods claimed in the instant application and in the reference application there are identical steps and materials (i.e., fusion protein) used. The portion of the specification that supports the recited method claimed in claims 1-3, 8-9 and 25 of the reference patent application 09/742,689 (US Pub 20010039250) includes embodiments that would anticipate the method claimed in claim 24 of the instant application. Claim 25 of the instant application listed above cannot be considered patentably distinct over claims 1-3, 8-9 and 25 of the reference application when there is specifically recited embodiment that would anticipate mainly claim 25 of the instant application. Alternatively, claim 25 cannot be considered patentably distinct over claims 1-3, 8-9 and 25 of the reference application when there is specifically disclosed embodiment in the reference application that supports claims 1-3, 8-9 and 25 of that application and falls within the scope of claim 25 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-3, 8-9 and 25 of the

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reference by making it more broader. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-3, 8-9 and 25 of the reference application.

Conclusion

None of the claims are in condition for allowance.

Since applicants have not filed any Terminal Disclaimer, disclaiming the patent terms of the above patent and the application, Examiner continues to maintain the above rejection for reasons of record.

As requested by the applicant a copy of the Form 1449 filed on 11-29-01 is enclosed herewith .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



MANJUNATH RAO
PATENT EXAMINER

Manjunath N. Rao, Ph.D.
May 18, 2004